

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

v.

BARRY J. CADDEN, et al.

Defendants.

CRIMINAL NO. 14 CR10363-RGS-JCB

**DEFENDANTS' MOTION IN LIMINE
TO EXCLUDE EVIDENCE OF NON-STERILE TESTING RESULTS**

Undersigned defendants hereby move, *in limine*, to exclude evidence of ARL or FDA out-of-specification non-sterile testing results (“OOS Results”) including the government’s proposed summary exhibits 824 (“Summary of Allegedly Contaminated Methylprednisolone Shipments”), 825 (“Summary of Shipments of Other Nonsterile Drugs from NECC”), and 828 (“Summary of Lots that Exceed Logged Formula Worksheet”) pursuant to Fed. R. Evid. 401 and 403.¹

Introduction and Summary of Argument

As set forth in more detail below, these summary exhibits are irrelevant to, and seek to unfairly prejudice, the remaining defendants who are charged with racketeering and racketeering

¹ As the government admitted in its briefing on Cadden’s various motions *in limine* and in its August 24, 2018 letter to defense counsel enclosing its Exhibit List, the ARL testing results of uncharged shipments were not Fed. R. Evid. 404(b) evidence. *See* Docket No. 827 (“Cadden again mischaracterizes this critical evidence of [NECC’s] repeated out-of-specification results as 404(b) evidence. It is not 404(b) evidence.”); *see also* August 24, 2018 letter (“To be clear, the government views all of this evidence as intrinsic to, and/or direct evidence of, the charged offenses.”). Nor could the evidence be considered Fed. R. Evid. 404(b) evidence here absent a connection between the remaining defendants and the specific shipment of drugs identified. *See U.S. v. Ramirez-Rivera*, 800 F.3d 1, n.38 (1st Cir. 2015).

conspiracy (Counts I and II)² with summary evidence of allegedly non-sterile results for only steroid medicines that they had no role in making. The OOS Results are not relevant to Count I as charged against the Remaining Defendants because they involve only steroids made by Glenn Chin, which are part and parcel of the methylprednisolone acetate enterprise identified by the Court in its Memorandum and Order on Defendants' Joint Motion to Exclude Evidence of Patient Harm Related to Methylprednisolone Acetate, Docket No. 1495. The OOS Results are also not relevant to Count II because they were not reasonably foreseeable – the government's own summary exhibits do not identify any non-sterile result for any drug prior to 2012, and all uncharged non-sterile evidence relates to steroids. There was not any non-sterile result for any drug in any year prior (for any pharmacist). The OOS Result evidence is unfairly prejudicial because it improperly seeks to assert a guilty-by-association inference against the Remaining Defendants with non-sterile test results for drugs made by their supervisor, that they did not know about, were not responsible for, and relate to a different enterprise altogether.

The government's proposed summary chart 824 is a "summary of alleged contaminated methylprednisolone shipments" (attached hereto as Exhibit A). As made clear in paragraph 42 of the Indictment, only Cadden and Glenn Chin are alleged to have been part of the scheme to defraud customers regarding methylprednisolone acetate. The Court recognized that "the substantive RICO allegations, although set out under an umbrella Count I, define two separate and distinct racketeering enterprises." Docket No. 1495 at 2. This proposed summary highlights results of tests for methylprednisolone acetate made only by Glenn Chin in a unique location, using a unique process. The government's proposed summary exhibit 825 (attached hereto as

² This includes Gene Svirskiy, Christopher Leary, Joseph Evanosky, Sharon Carter, and Alla Stepanets (the "Remaining Defendants").

Exhibit B) is similar.³ The exhibit contains non-sterile results of only uncharged steroid medications (the chart lists the steroids Betamethasone S.P., Betamethasone Repos, and Triamcinolone A.C.) Again, these compounded medications were made by Glenn Chin, the supervising pharmacist. *See, e.g.*, Chin Trial Tr. Day 24, Oct. 20, 2017, at 51 (closing argument by government describing Chin as “the only one who made the steroids”).

Unlike Cadden and Chin, the Remaining Defendant pharmacists and pharmacy technicians were not owners or supervisors of NECC, and were not responsible for NECC’s testing policies and procedures. None of the Remaining Defendants interacted with ARL, the outside testing lab used by NECC, or the non-sterile OOS Results themselves, and there is no evidence that any of the Remaining Defendants were informed of any of the OOS Results at issue. Contrary to the government’s stated intent, this evidence cannot be “intrinsic” to any crime charged against the Remaining Defendants.

Thus, any evidence of these results will be irrelevant, misleading, and unfairly prejudicial. The introduction of this type of evidence will also dramatically, and unnecessarily, lengthen the trial in this matter given the scale of evidence present on the government’s proposed exhibit list concerning sterility issues with steroid drugs; introduction of any non-sterile OOS Result will necessarily require each defendant to establish that he or she did not have anything to do with those steroid drugs at issue. If the Court is inclined to allow any OOS Results into evidence, the Court should revisit its previous ruling on this issue from the Cadden case (Docket No. 916). More specifically, the Court should revisit this ruling in light of the significant differences between the positions of the Remaining Defendants as compared to Cadden and Chin

³ The government’s proposed summary exhibit 828, “Summary of Lots that Exceed Logged Formula Worksheet” should also be excluded because it is not relevant. The exhibit identifies approximately twenty lots for which the milliliters dispensed allegedly exceeds the milliliters made. Once again, all of these lots are only steroids (the same three types identified in proposed exhibit 825). *See* Exhibit C, attached hereto.

and their roles with respect to compounding steroid medications, and require that: (1) any test result involves a medicine that one of the Remaining Defendants had a specific role in making; and (2) the result had been communicated to one of the Remaining Defendants.

Legal Standard

“Evidence is relevant if (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action.” Fed. R. Evid. 401. “Irrelevant evidence is not admissible.” Fed. R. Evid. 402. Even if evidence is relevant, it must overcome the restrictions of Fed. R. Evid. 403 – “[t]his rule requires the trial court to exclude the evidence if its probative value is substantially outweighed by the danger of unfair prejudice,” and permits the court to exclude evidence if its probative value is substantially outweighed by confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.” *U.S. v. Varoudakis*, 233 F.3d 113, 121 (1st Cir. 2000) (internal quotations and citations omitted).

Argument

I. The non-sterile OOS Results are not relevant to the Remaining Defendants, who were not involved with the results identified in the summary exhibit.

Contrary to the government’s prior argument that evidence of the non-sterile OOS results are “direct” evidence of the pattern of racketeering, the non-sterile OOS Results of which the Remaining Defendants were not aware, and for drugs which the Remaining Defendants were not involved, are neither probative of the Remaining Defendants’ intent nor evidence of the elements of crimes for which the Remaining Defendants are charged. As the government argued in opposition to Cadden’s motion to exclude the same test results, Cadden’s receipt and awareness of the non-sterile OOS Results was probative of his intent to engage in a mail fraud scheme: “the government should [] be allowed to present evidence of the other drugs ... in order to prove

the RICO and RICO conspiracy counts as well as the mail fraud scheme. This evidence is critical and necessary to prove the charged counts and is highly probative of defendant Cadden's reckless intent and intent to defraud." Docket No. 827, at 2. The government theorized that, because "Cadden received ARL's non-compliant test results, which came with markedly increased frequency in the summer of 2012, [and] ignored them," therefore "evidence of these results and shipments are direct, highly probative, and critical evidence of defendant Cadden's intent for the RICO, RICO Conspiracy, and mail fraud counts, as well as evidence of the mail fraud scheme charged in the Indictment." *Id.* at 3 (emphasis added).

It is the opposite here. These results were not received, let alone ignored, by the Remaining Defendants. Non-sterile OOS Results for drugs which the Remaining Defendants did not make, did not know about, and thus were not involved in, cannot be direct or highly probative of their intent to enter into a mail fraud scheme.

The OOS Results, which involve only steroids, are related to the first enterprise concerning the methylprednisolone steroid injections identified by the Court in its order excluding evidence of patient harm. *See* Docket No. 1495 at 2 ("The first, which is set out in paragraphs 40 through 62, alleges ... second-degree murder related to shipment of the three lots of MPA ... [and] only Cadden and Chin, the head pharmacist and supervising pharmacist respectively of NECC" were charged in this scheme). A plain reading of the Indictment supports this distinction. In describing the methylprednisolone scheme, the Indictment alleges that Cadden and Chin and NECC sold methylprednisolone, an injectable steroid, "which was *made in a manner* that did not meet the standards set forth in the USP" *Indictment*, ¶ 42 (emphasis added). The Indictment's allegations involving the Remaining Defendant pharmacists' conduct in any mail fraud scheme fundamentally differ: those allegations relate to shipping drugs "prior

to receiving the results of testing confirming the sterility and quality of drugs.” *Id.* ¶ 64. The allegations in the Indictment concerning the “ma[king]” of methylprednisolone and other steroids, and their corresponding non-sterile results, are therefore disconnected from the shipping-without-testing allegations⁴ and any corresponding non-sterile results (notably, *all* of the latter were charged as crimes in the Indictment).

The Indictment’s distinction between the methylprednisolone enterprise and the other alleged mail fraud enterprise (involving alleged “shipments of untested lots,” “shipments of expired drugs,” and “unlicensed pharmacy technician” shipments – all of which involve non-steroids) demonstrates that the Remaining Defendants did not participate in the compounding of steroids, and could not reasonably foresee that those steroids would be compounded in a manner that would cause them to be non-sterile and potentially cause catastrophic patient harm. As a result, the OOS Results evidence is not relevant to proving any crime by any of the Remaining Defendants with respect to the five shipments in 2012 of two allegedly non-sterile compounded medicines (polymixin-bacitracin and cardioplegia) identified in the Indictment. *See* Racketeering Acts 32-35, and 37.⁵

The Indictment’s allegations concerning the racketeering conspiracy Count 2 – a series of four clauses separated by semi-colons that track the “scheme[s]” identified in Count One – do

⁴ The other racketeering and racketeering conspiracy allegations are similarly disconnected from the making of steroids and any sterility issues. The additional racketeering “scheme[s]” identified in Count 1 are: (i) “using an ingredient that had expired,” *Indictment*, ¶ 67; and (ii) working alongside an unlicensed pharmacy technician, *see id.* ¶ 70.

⁵ The non-sterile, non-steroid drugs in the government’s proposed summary exhibit are otherwise identified in the Indictment as Racketeering Act 53 (Bacitracin to Good Shepherd Hospital, Ex. A at 4), Racketeering Act 58 (Potassium Chloride injectables to Port Huron Hospital, Ex. A at 7), and Racketeering Act 60 (Potassium Chloride bags to Sentara Norfolk General Hospital, Ex. A at 8).

not change the analysis.⁶ *Indictment*, ¶ 74. Such OOS non-sterile steroid results were not reasonably foreseeable; the government’s summary exhibits do not identify any non-sterile result for any drug prior to 2012, and all uncharged non-sterile evidence relates to steroids.

II. The non-sterile OOS Results are not relevant to the Remaining Defendants, who had no contact with ARL and were not responsible for NECC’s testing protocols and procedures.

NECC used an outside testing lab in Oklahoma called ARL to test certain of its products for, among other things potency and sterility. Barry Cadden chose ARL as the vendor around 2001. Cadden Trial Tr. Day 4, Jan. 9, 2017, Opening Statement of B. Singal, at 69-70 (“In this case, for the testing, he hired a company called ARL....”); Cadden Trial Tr. Day 19, Jan. 31, 2017, at 38:2-10 (testimony of Tommy Means). It is also undisputed that NECC’s director of quality, Annette Robinson, was the primary point of contact with ARL. *Id.*, at 105:9-10 (testimony of Tommy Means). She was the primary NECC employee responsible for the NECC testing program internally and externally with ARL. *Id.* Day 24, Feb. 7, 2017, at 56:15-22 (testimony of Corey Fletcher: “Q: And [Robinson] was the person who became the head of quality control at NECC, right? A: Correct. Q: And in that capacity, she was overseeing the samples from drugs being sent to ARL for testing, right? A: Correct. Q: She would be getting back to you the test results of those samples? A: That's correct.”).

It is also beyond dispute that all decisions as to what to test, how much to test, when to test, NECC standard operating procedures regarding testing, receipt of ARL test results, were all made by Cadden and Robinson, and not by any of the Remaining Defendants. *Id.* Day 28, Feb. 16, 2017, at 99:5-13 (testimony of A. Robinson); Chin Trial Tr. Day 9, Sept. 27, 2017, at 117:12-16 (testimony of C. Fletcher) (Robinson was “responsible for updating the SOPs”); Chin Trial

⁶ In fact, Count II, the racketeering conspiracy, does not incorporate by reference paragraph 42 of the Indictment, which is the one setting forth the mail fraud scheme with respect to methylprednisolone acetate. See *Id.* ¶ 72

Tr. Day 15, Oct. 5, 2017, at 122:6-20 (testimony of A. Robinson: “Q.[] And so you don't know who it was that made the arrangement with them? A. Probably was Barry. Q. [] Well, did anyone else ever direct you to send things to ARL than Barry Cadden? A. We -- well, no. Because all the samples went to them. ... Q. Well, did anyone else ever have the authority in that place to change the protocol with ARL? A. I don't believe so.”). It is also undisputed that Glenn Chin was the supervising pharmacist in the clean rooms.⁷

In each of the previous two trials, the government has introduced evidence of non-sterile OOS Results in an effort to prove that the owner and pharmacist in charge of NECC (Cadden) and the supervising pharmacist (Chin) were aware of these results and allegedly did not take sufficient steps to ensure sterility at NECC. It is noteworthy that Annette Robinson was neither charged by the government with any crimes nor was she identified by the government as an unindicted co-conspirator (none of the other pharmacists employed by NECC since 2006 are identified as unindicted co-conspirators either).

The Remaining Defendants did not engage in any of the conduct that would conceivably make the OOS Results relevant. Unless the government can establish that the Remaining Defendants made any decisions regarding testing, including what to test, how much to test, when to test, NECC standard operating procedures regarding testing, or were in actual receipt of ARL test results, those test results are not relevant in this trial. For this independent relevance reason, the Court should preclude admission of any ARL or other (FDA) non-sterile test results.

⁷ As the government has made abundantly clear: (i) “NECC was Barry Cadden’s baby” and “[e]verything happened because of Barry. Barry Cadden was NECC” (government opening statement, Cadden Trial Tr. Day 4, Jan. 9, 2017, 6:19-25); (ii) “Barry Cadden didn’t just know what was going on at NECC, he directed it. He was the master conductor for everything that happened there, from sales to compounding to hiring to dealing with the regulators.” (government closing argument, *id.* Day 46, March 16, 2017, 5:19-22) ; (iii) “[Glenn] Chin ran those cleanrooms. He ran the drug production inside of NECC. He was Barry Cadden’s right-hand man. And together you’re going to hear they were responsible for making all of NECC’s drugs” (government opening statement, Chin Trial Tr. Day 3, Sept. 19, 2017, at 24:3-7) (emphasis added); and (iv) “Glenn Chin was the licensed, trained supervising pharmacist who ran that clean room. He oversaw all of NECC’s sterile drug production along with Barry Cadden” (government closing argument, *id.* Day 24, Oct. 20, 2017, at 14:24-15:2).

III. Even if the Court finds that any non-sterile OOS Results are relevant, the Court should exclude them as unfairly prejudicial.

The non-sterile OOS Results are unfairly prejudicial in that the government is contending that the results reveal something negative about the production methods at NECC in total (as opposed to the production of the steroid medications), when all clean rooms involving human beings have some normal, expected rate of out-of-specification results, just like even the finest hospitals in the world have a background rate of infection. Unless the government can tether a particular result to a particular medicine involving a particular defendant, and show that the particular defendant was informed of the result, the evidence is entirely prejudicial as the result could not have formed the basis for that defendant's action or alleged inaction.

Admitting OOS Results into evidence that do not have any connection to any of the Remaining Defendants is unfairly prejudicial. The Eighth Circuit's ruling in *U.S. v. Flynn* is instructive, although the crimes in that case were far more violent and severe. Wary of the fact that "[t]he RICO statute has a tremendous potential for guilt by association," the Eighth Circuit concluded that admission of acts for which "[t]he Government presented no evidence linking [defendant]" were improperly admitted because "[t]he evidence obviously carried a prejudicial impact, yet in no way did it connect [defendant] to the enterprise." 852 F.2d 1045, 1054 (8th Cir. 1988). Specifically, the Court noted that the evidence of the possible murder of two individuals and the decision to murder a third, although it "tended to prove the enterprise element ... was not necessary to prove the existence of the enterprise." *Id.* Therefore, the Court concluded that the prejudicial value of the evidence outweighed its probative value.⁸ *Id.*

So too here. Whether or not Glenn Chin made non-sterile steroids in 2012 has no bearing on whether the Remaining Defendants committed the crimes charged in the Indictment. As this

⁸ The Eighth Circuit ultimately determined that the error did not warrant a new trial because of the limiting instruction provided to the jury.

Court noted in its ruling excluding evidence of patient harm, “[v]icarious liability, whether vertical, or as the government would have it here, inverted, has no place in the criminal law as our Rules of Evidence recognize ... in a capital prosecution, the sole object of which is the punishment of the delinquent, each man must answer for his own acts or defaults.” Docket No. 1495, at 16. Evidence of any non-sterile OOS Results for drugs that bear no connection to any of the Remaining Defendants, and therefore do not relate to any of their “acts or defaults,” therefore should be excluded.

Conclusion

For the reasons set forth above, the Court should exclude the government’s wholesale attempt to stain the Remaining Defendants with irrelevant and prejudicial test results for medicines that are not connected to them. If the Court is inclined to allow any test results into evidence, the Court should revisit its previous ruling on this issue from the Cadden case (Docket No. 916). A fair recalibrated test for the Remaining Defendants for any OOS Result results should require, before admission, that the government show: (1) any test result involves a medicine that one of the defendants had a specific role in making; (2) the result had been communicated to one of the Remaining Defendants.

Dated: September 18, 2018

Respectfully submitted,

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CERTIFICATE PURSUANT TO L.R. 7.1 AND 112.1

I hereby certify that I conferred with Assistant United States Attorneys George Varghese and Amanda Strachan in a good faith effort to resolve or narrow the issues raised by this motion pursuant to L.R. 7.1 and 112.1.

/s/ Jeremy M. Sternberg
Jeremy M. Sternberg

CERTIFICATE OF SERVICE

I, Jeremy M. Sternberg, hereby certify that this document was filed on September 18, 2018, via the ECF system, and was sent electronically on that date to the parties' counsel of record.

/s/ Jeremy M. Sternberg
Jeremy M. Sternberg